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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,363	09/06/2005	Kathryn Elizabeth Lawlor	18688	5197

272 7590 04/15/2009

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EXAMINER	
WOODWARD, CHERIE MICHELLE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,363	LAWLOR ET AL.	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,12,13,22,29-32 and 36* is/are pending in the application.

4a) Of the above claim(s) *22,29-32 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,12,13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/2009 has been entered.

Formal Matters

2. Applicant's Response and amendments to the claims and the specification, filed 1/27/2009, are acknowledged and entered. Claims 6-7, 9-11, 14-21, 23-28, 33-35, and 37-45 have been cancelled by Applicant. Claims 22, 29-32, and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-5, 8, 12, and 13 are under examination.

Response to Arguments

Objections/Rejections Withdrawn

3. The objection to the disclosure is withdrawn in light of the amendment to the specification.

4. The rejection of claims 1, 5, and 8 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of copending Application No. 10/559,771 in view of Devalaraja et al., US Patent Application Publication 20070059280 (published 15 March 2007, benefit to 20 March 2000) is withdrawn. The examiner apologizes for the inadvertent typographical error in the case number. The correct copending application number is 10/559,711. The examiner notes that the instant Applicant's representative is prosecuting both cases. In light of this fact and in light of the requirements of Applicant's representative to comply with **37 CFR 1.56**, the examiner has a reasonable belief that Applicant's representative would have realized the examiner's inadvertent typo. In any event, the examiner notes that copending application 10/559,711 was abandoned by Applicant and a Notice of Abandonment was mailed on 3/6/2009. Accordingly the provisional obviousness-type double patenting rejection is withdrawn as moot in light of the abandonment of the '711 application.

Objections/Rejections Maintained

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 8, 12, and 13 remain rejected under 35 U.S.C. 102(e) as being anticipated by Devalaraja et al., US Patent Application Publication 20070059280 (published 15 March 2007, benefit to 20 March 2000), as evidenced by Luross et al., (Immunology. 2001 Aug;103(4):407-16, Abstract only), as well as Meisenberg et al., (Blood 1992 May 1;79(9):2267-72; Abstract Only) and Campbell et al., (J Leukoc Biol. 2000 Jul;68(1):144-50, Abstract Only) (both cited for exemplary purposes in response to Applicant's arguments), for the reasons of record and the reasons set forth herein.

Applicant repeats previously presented arguments and argues that the '280 publication does not enable the method of treating inflammation or an autoimmune disease by administering to a mammal in need thereof a therapeutically effective amount of an inhibitor of G-CSF, including antibodies to G-CSF and G-CSFR (Remarks, p. 4). Applicant argues that the therapeutic methods taught by the '280 publication are based on an observation of the synergistic effect of exogenously added G-CSF on cytokine-mediated inflammation (Remarks, p. 5). Applicant argues that the '280 publication does not provide sufficient evidence with respect to the rule of endogenously produced G-CSF in inflammation and that the teachings of the '280 publication do not adequately support a method of treating a disease based on inhibiting endogenous G-CSF (Remarks, p. 5). Applicant also argues that the present application provides evidence for a role of endogenously produced G-CSF in promoting inflammation *in vivo* using G-CSF gene knockout mice (Remarks, p. 5).

Applicant contrasts the teachings of the '280 publication with the instantly claimed invention and argues that the '280 publication does not teach that G-CSF "alone" has the effect of driving bone marrow leukocyte production during inflammatory distress (Remarks, p. 5, last paragraph to p. 6). Applicant also argues that the examiner's evaluation should take into consideration the complex nature and relative unpredictability in the field (Remarks, pp. 6-7). Applicant argues copending applications of the '280

publication drawn to administering M-CSF (pp. 7-8). Applicant's arguments have been fully considered, but they are not persuasive.

First, Applicant's arguments drawn to non-cited art directed to administration of anti-M-CSF agents are entirely irrelevant to the instant claims, which are directed to a method of administering G-CSF antibodies, G-CSFR antibodies, or soluble G-CSFR and G-CSFR binding fragments.

Second, Applicant's argument that the '280 publication does not teach that "G-CSF alone" has the effect of driving bone marrow leukocyte production is spurious. The instant claims recite the transitional phrase "comprising" and are not limited to comprising an agent that affects "G-CSF alone." Additionally, the examiner notes that it is old and well-known in the art that G-CSF has a well-defined effect of driving bone marrow granulocyte production, whether it is endogenous or exogenously administered G-CSF (see, for exemplary purposes only in response to Applicant's arguments, Meisenberg et al., (Blood 1992 May 1;79(9):2267-72; Abstract Only). Moreover, Campbell et al., (J Leukoc Biol. 2000 Jul;68(1):144-50, Abstract Only) (cited for exemplary purposes in response to Applicant's arguments) show that administering exogenously administered G-CSF exacerbates collagen-induced arthritis in mice.

Applicant is reminded that a composition and its properties are inseparable and that the art clearly shows that both endogenously administered G-CSF and exogenously administered G-CSF have the same effect of driving bone marrow granulocyte production. Accordingly, treatment of arthritis where there is a prevalence of granulocytes (*i.e.* neutrophils), would be affected by administering a G-CSF antibody or G-CSFR antibody to block granulocyte production or function, as taught by the '280 publication. The '280 publication need not teach what is old and well known in the art in order to be enabled. The fact that the '280 publication does discuss what is well known in the art is sufficient for the disclosure of the '280 publication to meet the requirements of 35 USC 112, first paragraph.

As previously stated of record, with regard to Applicant's argument directed to the synergistic effect of exogenously added G-CSF, Applicant focuses its argument on only one alternative embodiment of the '280 publication. Applicant's attention is drawn to paragraphs 33-43 where the method of *in vivo* treatment is directed to treatment of inflammation caused by endogenous mediators. Treatment of rheumatoid arthritis is specifically discussed in paragraph 42 and "especially preferred inhibitors" are monoclonal antibodies to G-CSF or G-CSFR (paragraph 32).

As previously stated of record, with regard to Applicant's arguments that the '280 publication does not provide a showing based on an accepted experimental model of arthritis, such a showing is not required where the '280 publication teaches treatment of rheumatoid arthritis by administering antibodies

against G-CSF or G-CSFR and the art teaches that collagen-induced arthritis is an accepted animal model of rheumatoid arthritis, as evidenced by the Luross et al., publication, cited of record. Moreover, as stated above, the '280 publication teaches known models of transgenic and knockout G-CSFR mice (paragraph 3).

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647